The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) made a number of changes to the hospital outpatient department prospective payment system, including the following:

Payment Reform

- Use of Medicaid definitions for drugs under 1927.
    - In 2004, payment for a *sole source drug* must be between 88 and 95 percent of the reference average wholesale price (AWP) of the drug. In 2005, payment for a sole source drug must be between 83 and 95 percent of the reference AWP.
    - In 2004 and 2005, payment for an *innovator multiple source drug* may not exceed 68 percent of the reference AWP.
    - In 2004 and 2005, payment for a *noninnovator multiple source drug* may not exceed 46 percent of the reference AWP.
- Payments will apply to *radiopharmaceuticals* and to *drugs for which pass-through payments* were made before December 31, 2002.
- There will be a separate payment designated for *orphan drugs*.
- Payment for *drugs with no HCPCS code* assigned will be 95 percent of AWP.
- Hospital acquisition costs.
    - In 2004 and again in 2005, GAO will be required to survey hospital acquisition cost for each covered drug. GAO's recommendations are required to be reflected in the 2006 OPPS NPRM. No later than July 1, 2005, MedPAC must report on adjustment in APC payment rates for overhead costs and related expenses.

Special Payment for Brachytherapy

- Payment for brachytherapy devices furnished between January 1, 2004 and January 1, 2007 will be set at charges adjusted to cost.
- The Secretary must create separate APC groups based on the number, isotope, and radioactive intensity of these devices.
- By January 1, 2005, GAO must submit a report including specific recommendations for appropriate payments for brachytherapy devices.

Functional Equivalence

- The Secretary would be prohibited from publishing regulations that apply a functional equivalence standard to drug or biological in determining OPD transitional pass through payments on or after the date of enactment of the MMA unless such a standard was applied prior to enactment for the purposes of making pass-through payments in OPD. The Secretary may deem two drugs identical for the purposes of pass-through payments if two drugs are pharmaceutically equivalent and biologically equivalent as determined by the FDA.

Background:

Under the hospital outpatient prospective payment system (HOPD PPS), Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through payment, (2) as a separate APC payment; or (3) as packaged APC payment with other services. Transitional pass-through payments are supplemental payments to cover the

incremental cost associated with certain medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for at least 2, but not more than 3 years, the costs are incorporated into the APC relative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiopharmaceutical drugs and biological products; and new drugs and biological agents. Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95% of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision.

Functional Equivalence

In the November 1, 2002 Federal Register notice that established the 2003 HOPD PPS rates, a new anemia treatment for cancer patients was deemed no longer eligible for pass-through payments, because it was functionally equivalent, (although not structurally identical or therapeutically equivalent) to an existing treatment. The transitional pass-through rate for the drug was reduced to zero starting for services in 2003.